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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,985	01/29/2004	Daniel Perreault	S63.2-11023-US01	5338

490 7590 01/09/2006

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER
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COZART, JERMIE E

ART UNIT	PAPER NUMBER
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3726

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/767,985

Applicant(s)

PERREAULT ET AL.

Examiner

Jermie Cozart

Art Unit

3726

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 44-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,9,12,13,15,16,18 and 25-43 is/are rejected.
- 7) ☒ Claim(s) 3, 5, 7, 8, 10, 11, 14, 17, and 19-24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/1/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-43, drawn to a crimping apparatus and an apparatus for loading a medical device into a catheter delivery system, classified in class 72, subclass 402.
  - II. Claims 44-48, drawn to a method of crimping a medical device and loading the medical device, classified in class 29, subclass 428.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process can be performed using an apparatus which does not require blades.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Linda Lindquist on November 2, 2005, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-43. Affirmation of this election must be made by applicant in replying to this

Art Unit: 3726

Office action. Claims 44-48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "10" has been used to designate both a "plug" and a "crimping device" on page 6, lines 22-23 of the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

7. The disclosure is objected to because of the following informalities: On page 6, line 20, "plug" is objected to because there is no "actuation plug" present in the drawings, therefore it is suggested to change "plug" to - hub- ; On page 8, line 6,

"stresses" is objected to because it is the incorrect tense in the context used, therefore it is suggested to change "stresses" to - -stressed- -; On page 9, lines 3 and 6, "52" is objected to because it is the incorrect reference numeral used, therefore it is suggested to change "52" to - -50- -. Appropriate correction is required.

### ***Claim Objections***

8. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Misnumbered claims 5-44 have been renumbered 4-43 and their dependency has been changed accordingly.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by White et al. (US 6,171,234 B1).

White discloses an apparatus (10) for loading a medical device (30) into a catheter delivery system. The apparatus (10) has an alignment plug (22) with an external taper (i.e. outer tapered surface fig. 6) for matingly engaging said crimping

apparatus. The apparatus further comprising an introducer shaft (not labeled fig. 6) attached to knob (28). See column 3, lines 23 – 65, and figures 1 and 6 for further clarification.

Note that “constructed and arranged to matingly engage a crimping apparatus for reducing the diameter of said medical device from a first diameter to a second diameter prior to loading said medical device into said catheter delivery system” and “for matingly engaging said crimping apparatus” are recitations of the intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

11. Claims 1, 4, 6, 9, 12, 13, 16, 18, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Penner et al. (5,725,519).

Penner discloses an apparatus (16) for loading a medical device (12) into a catheter delivery system (BC), the apparatus (16) constructed and arranged to matingly engage a crimping apparatus (14) for reducing the diameter of the medical device (12) from a first diameter to a second diameter prior to loading said medical device (12) into the catheter delivery system (BC). The apparatus further comprises an introducer shaft (opening not labeled in fig. 4 through which an introducer plug 64 extends), the introducer plug has a lumen (60) through which the medical device is introduced. The introducer plug (64) is modular with the introducer shaft. The crimping apparatus (14) is an actuation hub, an internal taper (20, 30) for matingly engaging the loading apparatus

Art Unit: 3726

(16) via introducer plug (64). *See column 5, line 15 – column 7, line 49, and figures 1-4 for further clarification.*

12. Claims 12, 13, 15, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Ching et al. (US 6,510,722 B2).

Ching discloses a crimping apparatus (10) for reducing the diameter of a medical device from a first diameter to a second diameter. The apparatus has an actuation hub (14), and the actuation hub has an internal taper (see fig. 8). The apparatus comprises at least three coupled, movable blades (40) which form an aperture whose size may be varied. *See column 4, line 16 – column 6, line 55, and figures 1-3 and 8 for further clarification.*

Note that “constructed and arranged to matingly engage a loading apparatus for introducing said medical device into a catheter delivery system” and “for matingly engaging a loading apparatus” are recitations of the intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

13. Claims 25-35, 38, 39, and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Austin (US 6,360,577 B2).

Austin discloses an apparatus for reducing the diameter of a medical device such as a stent (180) from a first diameter to a second diameter, the apparatus comprising at least three coupled, movable blades (106) which form an aperture whose size may be varied, wherein at least one of the blades further comprises a tool (130, 166) which has

Art Unit: 3726

a conical flange adjacent the edge of at least one of the blades. The tool (166) is integral with at least one of the blades (106). Each of the blades has a tool (166) which is integral with the blade (106). The tool (130) is modular to all of the blades (106), and is attached to at least one of the blades mechanically. The tool is attached to at least one of the blades with a screw, thread, weld or adhesively. The tool (130, 166) is metallic or a combination thereof. The tool (166) is formed from the same material as the blades. The at least one tool (166) is formed from steel. A coating (not shown) may or may not be used which reduces the coefficient of friction since at least one tool (166) is formed from ceramic (i.e. zirconia ceramic). *See column 4, line 30 – column 6, line 17, and figures 3b - 4A and 8a-8c for further clarification.*

Note that “for matingly engage an apparatus for loading said medical device into a catheter delivery system” is a recitation of the intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



15. Claims 36, 37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Austin (US 6,360,577 B2).

Austin discloses the claimed invention except for the tool being formed from the materials listed in claims 36, 37, and 40.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the tool from the materials listed in claims 36, 37, and 40, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

#### ***Allowable Subject Matter***

16. Claims 3, 5, 7, 8, 10, 11, 14, 17, and 19-24 are objected to as being dependent upon rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of their respective base claim and any intervening claims.

#### ***Conclusion***

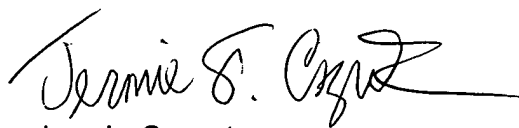
17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The reference cited on the attached PTO-892 is cited to show the loading of stents.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 571-272-4528. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm.

Art Unit: 3726

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc Jimenez can be reached on 571-272-4530. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jermie Cozart  
Examiner  
Art Unit 3726